



STATE OF WASHINGTON

DEPARTMENT OF HEALTH

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To: Pharmacist Investigators
From: Pharmacy Quality Assurance Commission
Date: March 16, 2018
Subject: Conducting Pharmacy Inspections

The Commission wants to thank our OII partners for your commitment to excellence and the mission of the Washington State Pharmacy Quality Assurance Commission. We are excited to embark upon our new inspection process with you and recognize that this is going to be a learning process for you, the Commission and licensees.

The Commission believes an important reason for routine pharmacy inspections is to educate the licensees about how to improve the quality of their practice to ensure the citizens of Washington State receive the best care possible and to better comply with our laws and regulations. The Commission firmly believes the goal of all Commission statutes and rules is to protect the health, safety and welfare of the public with regard to pharmacy practice.

The new inspection process supports this philosophy and is intended to be a collaborative experience that encourages learning by both the licensee and the investigator through interaction during the inspection process. Pharmacist investigators must make an effort to encourage continuous process improvement through active engagement and sharing of best practices. Through this collaboration, we will create better care environments for the citizens of Washington State. In addition, open, transparent and collaborative interactions between our licensees and our investigators will create a trusting relationship where questions can be raised to clarify understanding and ensure compliance with rule and statute.

We believe that applying this philosophy will increase trust between the licensed community, pharmacist investigators, and the Commission, which will lead to enhanced patient health and safety. In anticipation of beginning this process, we wanted to provide some specific guidance from the Commission to ensure solid alignment between the regulated community, the Commission, staff and our OII partners on conducting routine inspections.

Focus of Inspections

The Commission requests pharmacist investigators focus on patient safety related issues during routine pharmacy inspections. The Commission identified patient safety related questions on the general inspection worksheet, highlighting them in green. The focus of a pharmacy inspection will be answering the green highlighted questions, then other non-highlighted questions. *The only worksheet that currently has focus questions is the General Self-Inspection Worksheet and General Inspection Worksheet. We anticipate identifying focus areas for other practice settings by June of this year.*

We recognize that while you are on inspections, you may observe various actions occurring in a pharmacy that are not addressed by a question on the worksheet. If the action is a violation of law and/or rule, we included a space on your worksheets to note other areas of non-compliance. We do not intend to limit your abilities, rather want to focus inspections on certain patient safety elements and have inspections be a snapshot in time. We are hopeful this more directed approach will create efficiencies that ultimately increase the frequency of inspections by decreasing the amount of time spent on each inspection. For example, if each inspector conducts an average of one inspection per day, each facility will be inspected on a yearly basis.

Other site Inspections

Some pharmacies service multiple locations, i.e. HPACs and Nursing Homes. Hospitals who have HPACs listed on their hospital pharmacy license are required to conduct self-inspections, however they may follow the HPAC rules and choose a representative sample, or may choose to self-inspect all of their HPACs. If a hospital chooses to self-inspect a representative sample, that does not limit the selection of clinics by the pharmacist investigators.

Pharmacist investigators do not need to inspect nursing homes that contract with pharmacies specializing in long-term care pharmacy. If issues in documentation or other items arise at the long-term care pharmacy, then the Commission understands the investigator may need to do more research and follow-up. However, inspections of nursing homes is the function of the Department of Social and Health Services.

Delegation of Self-Inspections

We purposely left the delegation of filling out and conducting the self-inspection open to the responsible pharmacy manager (RPM). The RPM may choose whomever they feel is best able to perform this task. However, the ultimate responsibility for signing the worksheet(s) and affirming the contents of the completed self-inspection lies solely with the RPM.